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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,406	03/29/2006	Bernadette Verneau	065691-0397	3436

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EXAMINER	
ML, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,406	VERNEAU, BERNADETTE	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,17-23,26-32 and 34* is/are pending in the application.

4a) Of the above claim(s) *23 and 26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,17-22 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 9/3/2010 is acknowledged, with the cancellation of Claims 2-16, 24, 25, 33, and 35-36. Claims 1, 17-23, 26-32, and 34 are pending. Claims 23, and 26-32 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 1, 17-22, and 34 are examined on the merits**.

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 17-22, and 34 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 6/7/2010, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

In claim 1, Applicant recites "said formulation base consists essentially of at least one vegetable and/or mineral oil selected from soya oil, sunflower oil, corn oil, olive oil, nut oil, and a liquid paraffin, and a lipophilic additive selected from polyethylene glycol, beeswax, candelilla wax, carnauba wax, polyethylene oxide wax, petroleum wax, and glycerol palmitostearate, wherein said lipophilic additive is solid or pasty at room temperature, the

lipophilic additive amounting to approximately 10 to 20% by weight of the composition, and wherein the composition is a dosage form chosen between soft or hard capsules, and wherein the composition comprises approximately 5% by weight beeswax and approximately 5% by weight glycerol palmitostearate, based on the total composition" at lines 4-15. The recitation is very confusing, as it encompasses two ranges, one broad range and one narrow range. The narrow range demands "wherein the composition comprises approximately 5% by weight beeswax and approximately 5% by weight glycerol palmitostearate". The broad range requires "the lipophilic additive amounting to approximately 10 to 20% by weight of the composition". Since the Markush group of the lipophilic additives includes beeswax and glycerol palmitostearate, as long as the combination of beeswax and glycerol palmitostearate amounts to 10 to 20%, it would meet the requirement of the broad range. However, the combination of beeswax and glycerol palmitostearate can't be more than 10%, as beeswax or glycerol palmitostearate has to be 5% respectively in order to overcome the obviousness rejection. Thus the broad range and the new range do not agree with each other. Therefore, the composition has to "consisting of" 5% by weight beeswax and 5% by weight glycerol palmitostearate", and the Markush group of the lipophilic additives can not include beeswax and glycerol palmitostearate.

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Applicant argues that ""The test for definiteness under 3 5 U.S.C. 112, second paragraph, is whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification.' *Orthokinetics, Inc. v. SaJety Travel Chairs, Inc.,* 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986)." See M.P.E.P. § 2173.02. Here, the meaning of claim 1 would be clear to a skilled artisan" (page 7, last paragraph; page 8, 1st paragraph). Applicant also argues that "Claim 1 clearly provides for a "lipophilic additive amounting to approximately 10 to 20% by weight of the composition" and "wherein the composition comprises approximately 5% by weight beeswax and approximately 5% by weight glycerol palmitostearate" as lipophilic additives" (page 8, 2nd paragraph). Applicant argues that "These two limitations acting together require approximately 5% each of beeswax and glycerol palmitostearate, while allowing for other additional lipophilic additives such that up to 20% lipophilic additives may be present" (page 8, 3rd paragraph). Applicant further argues that "Accordingly, if the lipophilic additive content amounts to approximately 10% by weight of the composition, then only beeswax and glycerol palmitostearate are present" (page 8, 4th paragraph).Applicant at last argues that "Alternatively, if the lipophilic additive content amounts to more than approximately 10% by weight of the composition, then lipophilic additives other than beeswax and glycerol palmitostearate are also present to account for the lipophilic additive content above approximately 10% by weight of the composition" (page 8, 5th paragraph).

This is not pound persuasive. As stated above, the recitation is very confusing, as it encompasses two ranges, one broad range and one narrow range. The narrow range demands "wherein the composition comprises approximately 5% by weight beeswax and approximately 5% by weight glycerol palmitostearate". The broad range requires "the lipophilic additive

amounting to approximately 10 to 20% by weight of the composition". Since the Markush group of the lipophilic additives includes beeswax and glycerol palmitostearate, as long as the combination of beeswax and glycerol palmitostearate amounts to 10 to 20%, it would meet the requirement of the broad range. However, the combination of beeswax and glycerol palmitostearate can't be more than 10%, as beeswax or glycerol palmitostearate has to be 5% respectively in order to overcome the obviousness rejection. Thus the broad range and the new range do not agree with each other. Therefore, the composition has to "consisting of" 5% by weight beeswax and 5% by weight glycerol palmitostearate", and the Markush group of the lipophilic additives can not include beeswax and glycerol palmitostearate.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655